K023110

510(k) Summary

NOV 22 2002

Identification:

Date of Application:

September 18 , 2002

Applicant's and Name and Address:

Corey Stewart
Quality Assurance Manager
Digirad Corporation
9350 Trade Place
San Diego, CA 92126

Telephone and Fax Numbers of the Applicant

Telephone: (858) 537 – 2118
Fax: (858) 549 – 9789
Email: cstewart@digirad.com

Signature

Corey Stewart

Date 9/18/02

Device name and classification

Classification Code:

90 KPS

Panel Identification:

Radiology

Proprietary Name:

Cedars-Sinai Motion Correction (MoCo) Software

Common Name:

Gamma Camera System

Classification Name:

System, Emission Computed Tomography

Classification Class:

Class II Product

Substantial Equivalence

Predicate devices

	GE/SMV Cedars-Sinai BPGS and MoCo	ELGEMS Ltd. QPS/BPGS/MoCo Processing Applications
Product Code	90 KPS	90 KPS
510(k) Number	K010509	K003264

Device Description

The MoCo program is an independent, standalone software application developed by Cedars-Sinai Medical Center for the automatic and manual correction of SPECT acquisition motion artifacts from gated and ungated projection datasets. MoCo is the most popular motion correction application in the field of nuclear myocardial perfusion SPECT imaging. The software has the same indication for use and function as the Motion Correction function module of Mirage software (Segami Corporation, K972886), which is currently being used on Digirad 2020tc SPECT Imaging systems.

Intended Use

The Cedars-Sinai Motion Correction (MoCo) software program is intended for use in correcting patient motion artifacts in SPECT data acquired on a nuclear medicine gamma camera system.

Testing

Functionality tests were conducted to demonstrate that the MoCo software application functioned as per its specifications. All tests passed with the actual results substantially matching the expected results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2002

Mr. Corey Stewart
Quality Assurance Manager
DIGIRAD CORPORATION
3950 Trade Place
SAN DIEGO CA 92126

Re: K023110
Trade/Device Name: Cedars-Sinai Motion Correction (MoCo) Software, Model 111005
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: September 18, 2002
Received: September 19, 2002

Dear Mr. Stewart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX I. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 023110

Device Name: Cedars-Sinai Motion Correction (MoCo) Software Program on computer systems with a PC architecture, the Windows operating system and a PC X windows server software.

Indications For Use:

The Cedars-Sinai Motion Correction (MoCo) software program is intended for use in correcting patient motion artifacts in SPECT data acquired on a nuclear medicine gamma camera system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

prescription use ✓

David A. Kapp

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023110